ALASKA MEDICAID
PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting
Frontier Building, 3601 C Street, Room 880/890

DRAFT
MINUTES OF MEETING
May 18, 2007
8:00 a.m.

Committee Members Present:
Marvin Bergeson, MD
Heidi Brainerd, MS, RPh
Amber Briggs, PharmD
Richard E. Brodsky, MD
Robert Carlson, MD (telephonic)
Kelly Conright, MD
Lucy Curtiss, MD
Jeffrey G. Demain, MD
Traci Gale, RPh (telephonic)
Vincent Greear, RPh
R. Duane Hopson, MD
Ronald Keller, MD
Daniel Kiley, DDS, MPH (telephonic)
Andrej Maciewjewski, MD
Ronald J. Miller, RPh
Gregory R. Polston, MD
Sherrie Richey, MD
Janice L. Stables, MSN, ANP
George Stransky, MD
Trish D. White, RPh (telephonic)

Committee Members Absent:
Diane Liljegren, MD
Mark Bohrer, RPh
Thomas Hunt, MD

Others Present:
David Campana, RPh
Melinda Sater, PharmD - First Health

1. Call to Order

The meeting was called to order at 8:00 a.m.

2. Roll Call

A quorum was present.

3. Public Comment – Local Public/Local Physicians

Dr. George Stransky: Commented on herpes antivirals. The latest STD guidelines from the CDC came out recommending all three products being reviewed today for primary herpes treatment, suppression herpes treatment and recurring episodic herpes treatment. There is a new study showing Valtrex used in the last month of pregnancy reduces transmission, but this is not an FDA-approved indication yet. Famvir's active product has a half-life of 20 times longer than acyclovir or valacyclovir inside the nucleus of infected nerve cells. It also reduces herpetic neuralgia. The latest information from last month showed that women with HSV herpes and HIV/AIDS virus treated with acyclovir had diminished HIV vaginal shedding 2.8 times in plasma HIV levels in women co-infected with both, suggesting that treatment of herpes has a role in reducing HIV transmission. He suggested that a class effect be recommended.

Dr. Farah Madhani-Lovely from Alaska Native Medical Center: Commented on tiotropium bromide, one of the COPD drugs being reviewed today. The long-acting anticholinergic is recommended by the Global Initiative for Lung Disease for moderate COPD long-acting bronchodilators. In comparison with ipratropium, it is dosed once per day which increases patient compliance. It has been proven to improve exercise capacity and forced expiratory flow. She reported good effect with her patients using tiotropium bromide. She recommended it be maintained on the Medicaid list as patients feel better and are using rescue inhalers less frequently.

4. Re-Review of Leukotriene Inhibitors

There was no public comment on this class.

Dr. Melinda Sater presented the information on this class. There are two available products, and both are FDA approved for prophylaxis and treatment of asthma in adults. Zafirlukast is indicated for asthma in children age 5 and older and montelukast in children 12 months and older. The latter is also indicated for symptomatic relief for seasonal allergic rhinitis in adults and children 2 years and older and for perennial allergic rhinitis in adults and children 6 months of age and older. There are similar contraindications, warning, and adverse drug reaction profiles. Zafirlukast has a bit poorer drug interaction profile and must be dosed twice daily on an empty stomach. In Alaska, there were 891 claims in April, and 882 of them were for Singulair. There was little discussion previously and a motion was made for class effect with Singular preferentially preferred, which passed unanimously. There have not been significant changes in this class. Dr. Woodard uses Singular primarily in his practice and sees a significant role for it in the treatment of asthma and allergies in children.

Dr. Demain added that he does not use much zafirlukast, due to the issues Dr. Sater discussed above. It does not have the same preparations for children as in monoleukast. He supports continuing with what the committee currently approved.

DR. DEMAIN MOVED TO PREFER SINGULAIR BUT CONSIDER A CLASS EFFECT. SECONDED BY DR. BERGESON. MOTION CARRIED UNANIMOUSLY.

5. Re-review of Nasal Steroids

There was no public comment for this class.

Dr. Sater gave the First Health presentation on this category. Currently there are six available products in this class. Some are generic and some branded, but all agents are FDA-approved for the treatment of seasonal allergic rhinitis and perennial allergic rhinitis. Beclomethasone is indicated for prevention of recurrent nasal polyps following surgical removal and mometasone is indicated for treatment of nasal polyps. All are available as sprays and triamcinolone is available in aerosol form. Contraindications, warnings, adverse effects, and drug interaction profiles are similar for all products. All agents have similar efficacy and tolerability. In April there were 632 claims for drugs in this class. Preferred agents are Nasonex, generic flunisolide, and Nasacort AQ. Nasonex had 66.5% market share, flunisolide has 11.7%, generic Flonase has 11%, Nasacort AQ has 7%, Rhinocort Aqua has 2%, and Flonase has 1.2%. There were three claims for Beconase AQ. In previous discussions, the committee wanted to assure one aqueous solution would be available. Agents were deemed equivalent for efficacy. A motion for class effect including at least one aqueous solution and non-alcohol containing preparation passed unanimously. There have been no significant changes to this class since the last review. In speaking with Dr. Woodard, he considers the agents equivalent. He stated that fluticasone and mometasone might be safer molecules and adds that the fragrance in fluticasone can be problematic for some patients.

Dr. Demain concurred with Dr. Woodard's comments. As far as tolerance, with children it is important to use a preparation that does not sting. Having an alcohol-free preparation makes it more tolerable for children with fewer side effects. He thinks it is important to offer a non-fragrance, non-alcohol preparation for people who are sensitive to odors, but not necessarily allergic. In pregnancy, budesonide is usually preferred as a topical steroid, but that would be a consideration to be addressed. Nasonex is approved in younger children, but fluticasone is now approved down to 4 years, lower than the previous 6 years. He recommended a similar course as was taken last time.

DR. DEMAIN MOVED TO DECLARE A CLASS EFFECT WITH PREFER AN AQUEOUS PRODUCT WITHOUT ALCOHOL OR FRAGRANCE. NASONEX SHOULD BE INCLUDED FOR CHILDREN ALSO. DR. KELLER SECONDED. MOTION CARRIED UNANIMOUSLY.

Dr. Conright and Dr. Polston joined the meeting at this point.

Dr. Sater stated that if Nasonex is preferred for children, and if it comes in as a benefit of the bid process, then Nasonex will be approved for everyone.

6. Re-review of Inhalant Steroids

Randy Legg, Astra Zeneca: Commented on three products, starting with Pulmicort Respules which is available for nebulized product use. It is indicated from age 12 months to 8 years for asthma treatment. This is a twice a day medication that is in category B. Pulmicort Flexhaler has been launched. It is available as a 180 mcg dose as well as 90 mcg dose. It has a touch of lactose and as patients inhale it, it tastes sweet. It is still category B and initial indication is twice a day. It contains 120 puffs and it has a counter. Symbicort will be launched next month. It is a combination metered-dose inhaler in HFA formulation and it has budesonide and formoterol. It has two strengths available: 80 mcg of budesonide and 4.5 mcg of formoterol; the higher dose is 160/4.5. Both are used two puffs b.i.d.. The initial indication is for age 12 and up for asthma, specifically moderate to severe in patients that need combination therapy.

Dr. Demain asked about Symbicort, indicating there have been papers in European literature addressing its acute use. He asked if this was how it would be launched in the U.S., as maintenance therapy, rescue treatment

or both. Mr. Legg answered that it is maintenance therapy and is indicated in the U.S. as such at this time. Dr. Demain commented that with the development of this product, there have been concerns about the long-acting bronchodilators with increased risk of asthma death, which appear to be linked to the genetic arch 16 on the beta-2 receptor. He did not see literature addressing this with Symbicort. Mr. Legg commented that in the U.S. clinical trial there were no deaths from asthma or related to Symbicort. As part of the safety program for approval, there is a one-year high dose safety trial. Some patients used Holter monitors and ECG analysis and there were no incidents of cardiac effects or adverse events. That dose was 1280/36 mcg. Dr. Bergeson asked about deaths outside the U.S., and Mr. Legg answered that he was not aware of any. The U.S. product will be a pressured metered-dose inhaler.

Meredith Zarling, PharmD, Glaxo Smith Kline: Testified about Advair as preferred on the drug list for Alaska. Although there is no cure for asthma, it is highly manageable. The National Heart, Lung and Blood Institute panel of experts reviewed literature and issued clear guidelines on asthma management. These are not meant to be a stepped approach. Patients should be assessed for disease severity and appropriately managed based on their severity. For patients with mild persistent asthma, patients should be treated with a low-dose inhaled cortical steroid. For patients with moderate to severe asthma, treatment should be an inhaled glucocorticoid with long-acting beta agonist. This is based on the panel reviewing available published data and concluding strong evidence supports this. This is reaffirmed in the global asthma guidelines recently published. In the Gold trial, Bateman illustrated that guidelines to find control of asthma can be achieved in the majority of patients with uncontrolled asthma of all severities. Control was defined according to NIH and GENA guidelines in terms of lung function, symptoms, rescue medication use, exacerbations and adverse reactions. It was shown that adding a long-acting beta agonist to an inhaled corticosteroid versus increasing the dose of steroid over a year in over 3400 patients provided better control faster with fewer exacerbations. This was sustained throughout the trial.

Asthma symptoms have two main causes: inflammation and bronchoconstriction. Proper management requires medications that address both causes. Advair Diskus is easy to use dry powder inhaler which is also available in HFA metered dose formulation. This allows the patient to have both medications in a single puff. The patient cannot selectively discontinue the inhaled corticosteroid therapy if they want to enjoy the benefits of a long-acting beta agonist. Three strengths are available to allow the clinician to adjust the dose of inhaled corticosteroid. During clinical trials, Advair was significantly better than fluticasone or salmeterol alone or montelukast with or without inhaled corticosteroid in improving lung function and quality of life.

Poor compliance still remains a significant problem in patients with asthma. In two recently published studies by Stolak and Stemple, they found a significant increase in compliance with Advair Diskus compared with inhaled corticosteroid alone or compared to the individual components in separate inhalers. Advair 250/50 is also indicated for maintenance treatment of air flow obstruction in patients with COPD associated with chronic bronchitis. This makes it the only steroid product containing product approved for this use in the U.S. The number of asthma-related deaths has decreased by 25% since it peaked in 1996, the use of long-acting beta agonists has increased fivefold. Advair has a long-acting beta agonist that may increase the risk of asthma-related death. This is based on one primarily observational surveillance study, SMART, which is where the box warning is derived. The SMART trial compared Serevent and placebo when added to usual asthma care. The trial was done prior to the 1997 NIH guidelines, which strongly recommended use of inhaled corticosteroids. Only 38% of the African-American group and 49% of Caucasians were using inhaled corticosteroids at baseline. There was no difference in the primary outcome between groups. Asthma-related death was a secondary end point and the increase in asthma-related death in patients receiving salmeterol, 13 deaths out of 13,176 patients on salmeterol versus 3 out of 13,179 on placebo were seen.

Treatment of both the inflammation and the bronchoconstriction associated with asthma and with COPD are important and are advocated in national and global guidelines. Based on the data and recommendations of the guidelines, Medicaid patients are best served if Advair remains on the current PDL without restriction.

Dr. Demain asked for clarification about where Advair is used with COPD. Dr. Zarling stated that the Gold and ATS Guidelines recommended adding inhaled corticosteroid to a long-acting beta agonist when FEV1 is less than 50% in patients experiencing recurrent exacerbations. Dr. Demain asked about the switch to HFA, as it seems that there are similar results. He asked if the HFA is preferred over the Diskus. Dr. Zarling stated that the HFA formulation is geared toward those who do not like the dry powder inhaler or prefer the metered dose inhaler. At the request of Dr. Polston, Dr. Demain further commented that children cannot use the dry powder inhaler. Metered dose use with a spacer is better for children. Those under 5 cannot master the dry powder technique.

Dr. Demain stated that with new guidelines have been softened some with moderate asthma. One emphasis is to increase the inhaled steroid dose at least on equal terms or preferentially to adding the bronchodilator. This is one of the alternatives, still considered preferred, but there are three medications that can be added also. Dr. Zarling stated that the new guidelines have not come out. Preferred therapy for someone uncontrolled on inhaled corticosteroid is to add long-acting beta agonist or increase the dose of steroid, but adding a leukotriene modifier or theophylline. This is based on evidence and study review.

Dr. Brodsky asked about the long-acting products presented so far and asked Dr. Zarling to comment on why her product is better. Dr. Zarling stated that there are head-to-head trials to help with that. Advair is indicated down to age 4 where there is an indication for COPD. They have a metered dose and dry powder inhaler also.

Tatyana Kapustyan, PharmD, with Abbott Laboratories: Testified about Azmacort. The national asthma guidelines for patients with mild to moderate disease, initiating inhaled corticosteroids is the preferred approach. Adding additional therapies with progression is the next step. Initiating appropriate use of inhaled corticosteroids is very important, but her experience in ambulatory care confirms that use of inhalers is difficult for a lot of patients. There is a lot of education required. Another goal is to reduce systemic steroid use in these patients. Azmacort has a built-in spacer device. This ensures that the patient can get a consistent dose. It is indicated for children age 6 to 12 years and for adults. It comes in one strength with 240 doses per canister. This gives 75 mcg per dose. She asked that Azmacort be approved for the Alaska PDL.

Dr. Demain asked about the formulation since it became HFA. The HFA formulation is currently in development, so it is currently CFC preparation. This will be in solution.

Dan Manning, PharmD, Schering Plough: Testified about Asmanex. This is the only FDA approved ICS approved for once daily initiation and treatment for asthmatic patients. It is indicated down to age 12 and next year may have a lower indication. It has excellent safety profile and efficacy information. It has a total systemic bioavailability of less than 1%. At recommended doses, it has no HPA axis issues. Since it is dry powder inhaler, there is no coordination with inhalation. This makes it easier for some patients to use. It has a dose counter also.

Dr. Sater gave the First Health presentation for this category. There are six available agents. One agent, fluticasone, is available in combination with salmeterol. Budesonide is available in combination with formoterol. All agents are approved for maintenance and prophylactic treatment of asthma. There are differing

age qualifications, indicated in the packet inserts. Two major delivery devices include the dry powder inhaler and metered dose inhaler. All agents have similar efficacy and tolerability when used in equipotent doses. Other warnings, drug reactions and interactions are similar for all agents. In April there were 770 claims for drugs in this class, with Advair Diskus having 344 claims or 45% market share. Flovent HFA has 33%, Pulmicort nebulized product had 12%, two claims of QVAR had 7%, Pulmicort had 2.6%, and Azmacort had 1.3%. There were six claims for Asmanex and two claims for Advair HFA.

Flovent HFA, Advair Diskus, Pulmicort nebulizer, QVAR and Asmanex are preferred. There was extensive discussion last time about combination product procedure, the differing potencies of the agents and the need for nebulized product availability. The motion to include a low- to medium-potency and a high-potency agent and preferentially include Pulmicort Respules passed unanimously. Significant changes since the last review include Symbicort entering the market place. There have been a few changes in Pulmicort Turbuhaler versus Flexhaler. Dr. Woodard prefers the fluticasone and mometasone in his practice, due to more available dose options. He also supports Advair, feeling it safer due to fixed presence of the inhaled steroid with long-acting beta agonist. He is very optimistic about Symbicort and its role in asthma management.

Dr. Demain stated that he echoes Dr. Woodard's comments. He suggested that in looking at the guidelines, it is important to first establish control of the asthma with inhaled steroid prior to adding therapy. This was brought up on the older guidelines and will be in the current panel report. If a patient starts two- or three-drug therapy it makes it difficult to modify or fine-tune their treatment. Dr. Demain produced some copies of the new step approach to therapy and pointed out that they are based on control criteria. He reviewed this form with the committee and read it for the benefit of those attending the meeting via telephone.

Dr. Brodsky asked about the definitions for low-dose, medium-dose, and high-dose; he asked what fits into those categories and what is needed to treat asthma. Dr. Demain stated that there is a summary of that available, but it is important to look at dose and at potency. Some steroids are more potent than others. There is a need to select inhaled steroids with more than one dose regimen. Low to high potency would go from triamcinolone and beclomethasone to flunisolide and on to fluticasone as a high potency steroid. Mometasone is a high potency medication and budesonide is medium potency. He recommended that flunisolide not be recommended due to poor tolerance.

Dr. Brodsky asked what should be available. Dr. Demain recommended low dose, medium dose and high dose as well as combination therapy for the reasons discussed by the speakers. Studies looking at Symbicort and comparing it to Advair have mainly been done in Europe. There are some situations where Advair edged out Symbicort and others were the opposite. This mostly depended on timing used to measure PEF. He reviewed his opinion of the various available medications and what should be included.

Dr. Brodsky asked about the percentage of use of Pulmicort. Dr. Sater answered that Pulmicort nebs had 11.5% and the inhaler had 20 claims for the month of April. Dr. Bergeson asked about particle size and if this should be a consideration. Dr. Demain stated that there is emphasis on this and that a particle size of less than 2.2 microns is required to reach the smaller airway. This is probably the area most impacted by asthma. Beclomethasone size is 1.1, and budesonide is 2.2. When patients are doing well but still have symptoms of obstruction, it is recommended to add a second steroid that is smaller particle size. There is some clinical benefit, but perhaps no clinical study proof.

Dr. Brodsky asked about the committee policy about approving combination drugs when the individual agents are approved. Dr. Sater stated that usually the committee does not discuss combination drugs, but there can be

an exception in this therapeutic area. There will likely be a combination product approved anyway, in spite of how motions are formed.

Dr. Demain asked if this category was also being discussed for COPD. This is a different therapeutic approach that requires long-acting bronchodilator components without the inhaled steroids. Dr. Brodsky stated that this will be discussed later.

Dr. Conright asked about different dosage availabilities. She asked that if there are multiple dose ranges, then do the higher doses mean higher potency. Dr. Demain stated that high potency is based on binding to steroid inhaler. These mean a higher risk of systemic steroid effects. The dosing will affect this, but at certain doses there are systemic effects. Some drugs are impacted by other drugs also. He gave examples of this effect and explained how some people will be more sensitive to this effect. Lower dose-high potency will still give systemic issues. They are two separate things. Dr. Conright asked if there were not necessarily more side effects with higher doses in fluticasone as opposed to lower doses. Dr. Demain stated that there will be, but when one raises the dose of a high potency, there is a greater risk of systemic effect than if you raise the dose of a low potency. He stated that there is a chart that parallels each drug in their dose/potency range.

Ms. Brainerd discussed that in following evidence-based medicine, there will still be many times that the best worded motion will not fit a particular patient. She stated she is in favor of letting bids fall where they may. Writing "medically necessary" can be used to obtain any of the agents.

Dr. Demain commented that there are unique characteristics, for example with budesonide. This is necessary to carry as it is the only one in respule form for children and the only one appropriate for pregnancy. He stated it is also important to have multiple dosage forms to follow guidelines of low-, medium- and high-potency.

Mr. Greear asked if it was worth splitting the combination products. Dr. Brodsky stated that when there are other places with combination products, and the committee usually looks at components. If the components are on there, then the combination product gets approved. With this class, it is more than convenience with combination products, as there are apparently better outcomes with combinations. There may be a way to word the motion to include a combination product. Dr. Brodsky stated that having pediatric and Class B products available is good, but with every drug this consideration is raised. The committee has shied away from specifying this, but providers can write "medically necessary" to get these agents filled.

Dr. Conright stated that the committee had made the distinction before. Dr. Brodsky agreed that the committee had, but with every class the question does come up. Dr. Conright asked Dr. Demain to make a recommendation about low-, medium-, or high potency categories, or something with multiple dose ranges. Dr. Demain recommended carrying one low, one medium and one high potency. With steroids, he recommended considering mometasone, fluticasone; in medium potency, it is budesonide and flunisolide, but he encouraged not using flunisolide; for low potency, he recommended beclomethasone and triamcinolone. Picking one from each category, with the exception of not preferring flunisolide.

DR. DEMAIN MOVED TO INCLUDE A LOW TO MEDIUM POTENCY MEDICATION AND A HIGH POTENCY MEDICATION ON THE PDL WITH FLUNISOLIDE NOT PREFERRED.

Dr. Conright asked about the difference between preferring not to use flunisolide or preferring budesonide. Dr. Demain stated that there is no difference and the list will get budesonide, but flunisolide is not a good molecule.

If left to bidding, this drug may win out. Dr. Conright stated that with budesonide, there is pregnancy and pediatric coverage, which is a reason to prefer it. Dr. Demain agreed.

DR. DEMAIN RESTATED HIS MOTION AS "PREFER A LOW POTENCY INHALED STEROID, AND A HIGH POTENCY INHALED STEROID AND TO ALSO PREFER BUDESONIDE IN ALL FORMS." DR. CONRIGHT SECONDED.

Dr. Demain asked if that would exclude flunisolide. Dr. Brodsky stated it will not exclude it but this may have the low bid. Mr. Greear asked if this would affect the combination products. Dr. Sater and Dr. Brodsky stated that it could, but not in a restrictive way.

Dr. Demain asked if fluticasone is now a generic molecule. Dr. Sater stated that it was in the nasal spray. Dr. Demain asked if it is approaching a point where it will be available generically. The answer was inaudible. Dr. Brodsky stated that if fluticasone does not have a low bid, then 78% of the current market will be excluded with combination and individual products. Dr. Sater said that the committee can rest easily about that point.

MOTION CARRIED WITH TWO OPPOSED.

7. Re-review of Short-acting Beta 2 Agonists

Meredith Zarling, PharmD, GlaxoSmithKline: Gave testimony on Ventolin HFA. This is a short-acting beta agonist indicated for treatment and prevention of bronchospasm and prevention of exercise-induced bronchospasm in adults and children 4 years and older with reversible obstructive airway disease. Ventolin is the only one with a dose counter. This provides patients the ability to know the number of remaining doses in the rescue inhaler. With this advantage, Ventolin HFA should be available to Medicaid patients in Alaska on an unrestricted basis.

Steve Thompson, Sepracor: Testified about Xopenex HFA and requested it be added to the Alaska PDL. There are currently four short-acting beta agonists in an HFA device. Three are branded and there is no generic option available. Xopenex or levalbuterol is the only product that differs from the other branded products. Many doctors prefer Xopenex due to its increased efficacy, longer duration of action and fewer side effects. There is also clinical data showing reduction in hospital administrations and length of stay. The MDI transition to HFA units is happening quickly. This is one of the most frequently prescribed class of drugs in the U.S. With many manufacturers closing their operations, he offered that it would make sense to add Xopenex if one or more manufacturers is not able to meet the demand for this class of drug. Xopenex is available on the PDL for Idaho, Nevada, California and Washington state. He asked that the P&T committee approve this medication.

Dr. Demain stated that there were head-to-head comparisons with Xopenex compared to albuterol. It has been shown to provide significant improvement in patients currently using long-acting beta agonists. He asked Mr. Thompson why levalbuterol provides greater bronchodilatory effect. Mr. Thompson stated that this is a single isomer of albuterol and the S isomer has been shown in some clinical trials to be pro-inflammatory in effect. Since levalbuterol is the right isomer this would be the reason for the duration of efficacy in action. Dr. Demain asked about metabolic risks if the drug is overused. Mr. Thompson stated that he was not aware of any. He offered to get that information to the committee.

Dan Manning, Schering-Plough: Testified about Proventil HFA. Most of the products are very similar. Proventil is one of two products indicated down to age 4. Patients do not have to discard the inhaler two months after opening the pouch. Patients can use the 200 doses until it is done.

Dr. Sater gave the First Health presentation on this class of drugs. There are two delivery mechanisms available, inhalers and nebulizer solutions. There are still albuterol CFC inhalers out there, but most are switching to HFA products, and all will have to do so soon. There are four inhalers available and three nebulized available. All are indicated for treatment of bronchospasm. All are relatively selective for the beta 2 receptors and all agents have similar efficacy and tolerability. In Alaska, there were 1905 claims in April. Generic albuterol had 28.5%, Pro-Air had 27%, albuterol nebulization had 26%. Proventil HFA had 10% and Xopenex HFA had 3.2%. Ventolin HFA had 2.6%, Xopenex nebulization had 1.3% and there were 12 claims for AccuNeb, two for Maxair, two for Proventil and one for Alupent. The preferred agents are generic albuterol inhalers at this time and in generic HFA product. In previous discussions, HFA product was preferred and agents were deemed therapeutically equivalent.

There are no significant changes in this class. Dr. Woodard feels most patients can be appropriately managed with albuterol HFA and recommended this alone be added to the PDL. He tries to move all patients toward inhalers and away from nebulized products. He sees no downside to levalbuterol, if this is cost effective for the committee. Dr. Patricia Skala sent a letter asking that Xopenex HFA be added to the PDL.

Dr. Sater reiterated that if physicians write letters and anyone submits things to the committee, then the comments need to be submitted before the deadline on the web site. No further last minute submissions will be accepted, including those submitted on the day of the meeting.

Dr. Demain stated that albuterol has become the industry standard and HFA preparation is preferred for the past 18 months or so. Soon it will be the only one available. The use of short-acting bronchodilators needs to be in multiple dosage forms. The nebulized solution has a role, but it is not as frequently used as the metered-dose inhaler. Dr. Demain stated that he finds the use of levalbuterol helpful. Some patients are more sensitive to albuterol side effects.

Dr. Brodsky stated that there are other studies showing levalbuterol is no more effective than albuterol and the side effect profile is similar. He stated that there is not a big difference.

DR. DEMAIN MOVED TO PREFER ALBUTEROL IN ALL DOSAGE FORMS. DR. KILEY SECONDED.

Dr. Keller asked what the difference was between this motion and saying class effect. Dr. Demain stated that with class effect, there could be other drugs besides albuterol on the PDL. Dr. Bergeson asked if the motion could be class effect and include an HFA product. Dr. Demain stated he would be in favor of that.

DR. DEMAIN AMENDED HIS MOTION TO DECLARE CLASS EFFECT AND TO INCLUDE AN ALBUTEROL HFA PRODUCT. DR. CONRIGHT SECONDED.

Dr. Sater stated that if the motion included one HFA product on the PDL, that covers the bases.

DR. DEMAIN FURTHER AMENDED HIS MOTION TO DECLARE A CLASS EFFECT AND INCLUDE ONE HFA. DR. CONRIGHT SECONDED. MOTION CARRIED UNANIMOUSLY.

8. Re-review of Long-acting B2 Agonists

There was no public comment for this class.

Dr. Sater gave the First Health presentation on this class of medications. There are two available agents: salmeterol, which is also available in combination with fluticasone. Formoterol is available in combination with budesonide and they are available as separate agents. Both agents are indicated for maintenance treatment of asthma, exercise-induced bronchospasm and maintenance treatment of bronchoconstriction and bronchospasm in patients with COPD. Formoterol has more rapid onset of action; however, neither agent should be used as a rescue medication. Tolerability and efficacy are equivalent between the agents. In Alaska in April there were only 14 claims for these drugs. Serevent is the preferred agent and has a 43% market share, and Foradil has 57%. Previous discussions centered around safety and need for prior authorizations in this class. Motion to consider class effect with prior authorization required carried unanimously. New to this class is Symbicort. Dr. Woodard has no preference for either agent in this class and sees limited utility for this drug in his pediatric patient population.

Dr. Brodsky asked if the 14 claims were for single agents, and Dr. Sater stated this was the case. Dr. Curtiss asked what the prior authorization process was and what makes this a class to require that. Dr. Sater stated that there were safety issues with the use of long-acting beta agonists alone as monotherapy. The decision was made that the prior authorization criteria would include an inhaled corticosteroid concurrently in use to get approval for one of these drugs.

Dr. Demain stated that there is an exception for COPD patients, who use this as monotherapy. Dr. Sater stated that the corticosteroid criteria was added for asthmatic patients. COPD patients have the clinical criteria that they can receive these drugs as monotherapy. Dr. Demain stated that he primarily uses this agent in combination, except for COPD patients. However, many COPD will not be affected by this committee. There is sometimes patient preference for formoterol. Both are appropriate and effective with equal efficacy. One downside to formoterol is a cumbersome inhaler. This is a barrier to some patients, but the device will be changing and may eliminate this barrier.

DR. KELLER MOVED TO CONSIDER CLASS EFFECT. DR. DEMAIN SECONDED ADDING THAT PRIOR AUTHORIZATION BE REQUIRED. DR. KELLER AGREED TO THE ADDITION.

Dr. Sater stated that every prescription in this class now requires preauthorization. The criteria is set in place by which the prescription is approved. Dr. Demain stated that there was a dramatic decrease in the use of monotherapy in the last four years. This was brought about mostly due to education. He stated that maybe the preauthorization is not necessary and asked the committee for their comments. Dr. Conright asked if the prior authorization was kept, then only one medication is approved for age 4. She asked if this would require writing "medically necessary" for children. Dr. Keller stated that the use of these medications in children is very small. Prior authorization covers this adequately. Dr. Demain stated that the benefits of long-acting dilators in children is marginal compared to adults.

The committee then discussed if the prior authorization was still needed. Dr. Briggs stated that in her experience the education is not there yet.

MOTION CARRIED WITH ONE OPPOSED.

9. Re-Review of COPD inhalant drugs

Patrick Voida, National Medical Scientist with Behringer Ingelheim: Testified telephonically about Spiriva. This drug is indicated for the long-term once daily treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema. The Gold guidelines recommended stepwise approach to management of COPD based on disease severity. Appropriate therapy includes patient education, appropriate vaccination, smoking cessation counseling and, for mild disease, initiating with short-acting agent as needed for symptoms control. The addition of maintenance therapy with one or more long-acting agents is recommended as well as pulmonary rehabilitation once the patient has reached moderate to severe stages of COPD. In severe and very severe disease, the presence of repeated exacerbation, inhaled glucocorticoid steroids are added. For initiating maintenance therapy, long-acting agents are recommended by Gold and other guidelines, as they are more effective and convenient for treatment than short-acting bronchodilators. Spiriva is a long-acting bronchodilator and is recommended as first line maintenance therapy. In clinical trials, it showed sustained superior pre-dose FEV1 lung function improvements throughout the year compared to ipratropium. It showed improved bronchodilation in COPD patients with a greater improvement in peak FEV1 from baseline compared to salmeterol and of a 12 week study that was conducted. Additional six month trials showed greater improvement in peak FEV1 from baseline compared to salmeterol and that was an 83 ml difference. Spiriva has been shown to improve pulmonary function and decrease hyperinflation, which leads to increase in median exercise endurance time compared to placebo. This was confirmed by a second study. However, the impact of the increase on endurance time in an exercise lab and how it translates into activities of daily living has not been established. Spiriva is contraindicated in patients with a history of hypersensitivity to atropine or derivatives. He reviewed the side effects in various populations. He reviewed the safety profile of Spiriva also.

Dr. Sater gave the First Health presentation on this class. There are two available agents: tiotropium and ipratropium. The latter is available as Atrovent, Atrovent HFA and in combination with albuterol in Combivent and DuoNeb. There are similar adverse event profiles with the only difference being the duration of action. Three to four hours, sometimes up to six hours for ipratropium and 24 hours for tiotropium. There were 310 claims for drugs in this class last month. Combivent got 50% market share, Spiriva 18%, DuoNeb 13%, ipratropium nebs 9%, Atrovent HFA 4%. Previous discussions centered around Spiriva and its benefit to patients with moderate to severe COPD. Motion was made to include all drugs, and that passed unanimously. There have been no significant changes to this class. There was no expert opinion testimony submitted.

Dr. Demain stated that he uses Spiriva, and for COPD management he believes it is the best step taken in COPD management in some years. It is well tolerated and patients have perceived benefit. Studies show a 12% improvement in FEV1 and improvement inhaled breath. Dr. Demain had the Gold study available for the committee to review.

DR. KELLER MOVED TO CONSIDER CLASS EFFECT WITH SPIRIVA PREFERRED AND ONE COMBINATION AVAILABLE. DR. CONRIGHT SECONDED.

Ms. Stables asked if this would get a liquid formulation for the nebulizer. Dr. Sater stated that generic ipratropium would be available. Ms. Brainerd asked about tiotropium and ipratropium concurrent use, which is not recommended. Standard drug packages do not pick up that interaction and it is very common for patients to receive both. Dr. Demain stated there is a strong contraindication for these. Ms. Brainerd said they do not flag

in a typical drug interaction. Mr. Campana stated that the DUR committee should look at this. Dr. Sater stated that they looked at this and it can be coded into the software.

MOTION PASSED UNANIMOUSLY.

10. Re-review of Antifungals

Josh Shiela, Sanofi Aventis Dermatology: Testified via telephone about Penlac nail lacquer. This is a topical antifungal containing 8% ciclopirox. It is indicated for treatment of mild to moderate onychomycosis of the fingernails and toenails. 35 million people are affected by this. This is the only product that is FDA-approved for treatment of onychomycosis. There are other topicals with antifungal effects, but Penlac penetrates the nail bed to reach the fungal area. It is safe and a nonsystemic treatment. There are no reported drug interactions or liver damage associated with Penlac and no liver function tests are required. This is relevant to diabetic patients on multiple medications. This medication is also cost effective with one bottle treating one to two nails for a year.

Dr. Sater gave the First Health presentation on this class. There are four available agents with one topical. The griseofulvin is fungistatic and the other oral meds are fungicidal. Penlac is a chelating agent that inhibits fungal growth. Different formulations of griseofulvin alter the GI absorption of that drug. It has a less attractive and unique adverse drug reaction profile. Adverse drug reactions of Lamisil and Sporanox are similar. Drug interaction profile was extensive with Sporanox but significant interaction profile with Lamisil and griseofulvin also. There were 58 claims for drugs in this class in April. Lamisil has 71% market share and Grifulvin V has 10%. There were five claims for Sporanox, five claims for Penlac, and one for Gris-PEG. Previous discussions emphasized safety issues. There was a motion to include a griseofulvin product and Lamisil and that passed with one opposed. Changes to this group include the addition of Penlac.

Dr. Conright asked Dr. Sater to repeat the motion from last year and the rationale. Griseofulvin was added to have a liquid treatment for pediatric patients and Lamisil because it has a slightly more attractive drug interaction profile.

Dr. Demain asked about fluconazole, and Dr. Sater stated that this is useful but not for onychomycosis. Diflucan is not available on the PDL currently but the claims get paid. Dr. Brodsky asked why Lamisil was included last time, and Dr. Sater answered that drug interaction profiles was the main reason. She states that she would like to hear from infectious disease physicians or dermatologists. Dr. Bergeson asked if these were for onychomycosis or tinea capitis. Dr. Sater said this was not known. Dr. Conright asked what percentage of claims were for Lamisil. Dr. Sater stated it was 71%, but Dr. Demain pointed out this is the preferred product. Dr. Demain stated he does not treat a lot of patients with this class. Dr. Conright does not either, but she prefers things with minimal side effect profiles. She would like to have a topical agent included.

DR. DEMAIN MOVED TO DECLARE CLASS EFFECT. MS. STABLES SECONDED. **MOTION PASSED UNANIMOUSLY.**

10. Re-Review of Antivirals

Eric Egeland, GlaxoSmithKline: Testified about Valtrex. He referred to Dr. Stransky's earlier testimony about CDC guidelines. Copies were distributed to the committee. Valtrex is not acyclovir. It offers consistently greater bioavailability than oral acyclovir at any dose. When Valtrex is dosed at 1 gram t.i.d., Valtrex achieves

plasma acyclovir levels similar to those of IV acyclovir. The CDC guidelines state that 50 million people have genital HSV infection and the majority infected have not been diagnosed with genital herpes. Many have mild or unrecognized infection that shed intermittently in the genital tract. Majority of these infections are transmitted by those unaware they are infected. Valtrex has been shown to decrease rate of HSV transmission in specific cases. The combination of Valtrex and patient education is key to decreasing this rate also. He asked that Valtrex be included on the PDL.

Dr. Brodsky asked about suppression in the study and how several studies compared valacyclovir or famciclovir with acyclovir and the results show comparable outcomes. Efficacy is similar for all drugs, but Valtrex is once a day. Mr. Egeland stated that GSK has investigated with three different trials that 500 mg or 1 gram dose will suppress or cut back in transmission if there is indication.

Dr. Demain asked about Valtrex's ability to decrease in HSV transmission to infants and what medication can be used in pregnancy. Mr. Egeland stated that Valtrex is not indicated for that specific use.

Soraya Kanakis, PharmD, Novartis: Testified telephonically about Famvir. Famvir is indicated for the treatment of acute herpes zoster or shingles and for treatment or suppression of recurrent genital herpes in immunocompetent patient and for the treatment of recurrent mucocutaneous herpes simplex infections in HIV-indicated patients. In the herpes zoster trials, Famvir demonstrated significantly shorter median time to lesion healing when compared to placebo. Famvir 500 mg t.i.d. showed improvement in five days versus seven days in placebo. Other parameters were shortened. The current genital herpes trials showed Famvir significantly more effective versus placebo in time to cessation of viral shedding, time to healing and time to loss of symptoms. Efficacy of Famvir for genital herpes suppression was studied in two one-year pivotal trials. Recurrence rates for Famvir 250 mg b.i.d. were higher than with placebo. In the clinical trials for HIV-infected patients with recurrent mucocutaneous herpes simplex virus infection, patients were treated with Famvir 500 mg b.i.d. for 7 days or oral acyclovir 400 mg five times a day. These two therapies were comparable. The single day dosing for recurrent herpes showed patients treated with Famvir 1000 mg b.i.d. compared to placebo groups had 23% aborted lesions. Single dose treatment for herpes labialis results were reviewed also. The majority of patients are not compliant with suppressive therapy and many discontinue treatment. The CDC guidelines emphasize patient involvement. Famvir has 77% bioavailability. The active antiviral compound is penciclovir with good penetration. The intercellular half-life is 10 hours for HSV 1 and 20 hours for HSV 2.

Dr. Sater gave the First Health presentation on herpes antivirals. There are three available agents, which are all FDA indicated for treatment of genital herpes infections, acute and suppressive. Acyclovir is indicated for varicella and varicella zoster. Valacyclovir is indicated for varicella zoster. Acyclovir is available in a number of forms. Efficacy, adverse drug reaction profiles, and drug interactions are similar for all agents. There were 239 claims in Alaska for drugs in this class. Valtrex had 40%, acyclovir has 37% market share, Famvir had 12% and Zovirax topical has 10%. Last year, there was a class effect declared with recommendation to include one oral agent.

Dr. Keller asked if one oral agent meant one oral suspension. Dr. Sater stated that if there was a class effect declared, there was concerned with receiving Zovirax cream, so the oral agent was included. Dr. Keller states that he sees a need for an oral suspension.

DR. KELLER MOVED TO CONSIDER CLASS EFFECT AND INCLUDE ONE ORAL AGENT. DR. BERGESON SECONDED. MOTION CARRIED UNANIMOUSLY.

11. Re-review second and third generation cephalosporins:

There was no public comment for this class.

Dr. Sater gave the First Health presentation second generation cephalosporins first. There are four available agents in this class. Second generation cephalosporins show less gram positive coverage but extended gram negative coverage compared to first generation cephalosporins. Three of the agents are available in generic form. Eleven major FDA approved indications for drugs in this class exist. For community acquired infections, these agents can be considered therapeutically equivalent. Adverse drug reaction profiles are somewhat poorer with regard to cefaclor, but otherwise contraindications, drug interactions and warnings are similar in most agents. In previous discussions, the adverse drug reaction of cefaclor and taste problems associated with suspensions was emphasized. Cefzil suspension was preferred, cefaclor was excluded and the motion carried unanimously. There have been no changes in this class. The current preferred agents are Cefzil tablets, Cefzil suspension and cefuroxime tablets. There were only 26 claims in April in Alaska with 38% for cefuroxime has 31% for Ceftin suspension, 19% for Cefzil suspension, and 11.5% for Cefzil.

DR. KELLER MOVED TO DECLARE CLASS EFFECT, BUT NOT INCLUDE CEFACLOR. CEFZIL SUSPENSION WILL BE INCLUDED. DR. BERGESON SECONDED. MOTION PASSED UNANIMOUSLY.

Dr. Sater gave information about the third generation cephalosporins. There are five available agents for this class. Indications vary by agent. Therapeutic efficacy is equivalent among all agents. Adverse drug reaction profiles, warnings, and contraindications are all similar for the drugs in this class. There were 509 claims last month for 3rd generation cephalosporins. Omnicef suspension had 80%, followed by Omnicef tablets at 17% and a handful of claims for the rest of the drugs in this class. Omnicef tablets and suspension are preferred, as is Suprax suspension. There was a brief discussion about treatment of STD and otitis media last year. Agents were deemed therapeutically equivalent. Omnicef suspension was preferred due to taste issues. Motion carried unanimously. New to this class is generic Omnicef which will be out soon, if not already.

DR. CARLSON MOVED TO PREFER OMNICEF BUT DECLARE CLASS EFFECT. SECONDED BY DR. BERGESON. MOTION PASSED UNANIMOUSLY.

12. Re-Review of second and third generation quinolones:

Laura Litzenberger, PharmD, Scientific Liaison for Ortho-McNiel Janson: Testified about Levaquin. This has been available in the U.S. since 1996. This has been the preferred 3rd generation quinolone on the Alaska PDL for the past five years. This has a high formulary compliance. Levaquin has 11 indications, including respiratory and GU applications. This includes two high-dose short-course indications with 750 mg q.d. for 5 days. This is for both community-acquired pneumonia and acute bacterial sinusitis. This has also been studied in acute exacerbation of chronic bronchitis. The new guidelines published in March recommended Levaquin for community-acquired pneumonia. The benefits of high dose short course therapy include faster symptom resolution compared to a 10 day course. There may be increased patient compliance and potential to lower bacterial resistance. There is data from the TRUST study suggesting nationally 99% of strep-pneumo isolates are susceptible to Levaquin. Safety profile has been demonstrated in 430 million patients worldwide. Cardiac safety has been verified in high risk elderly patients. This compared to Avelox with significantly increased QTC. Levaquin is 4% excreted in the intestinal tract, compared to Avelox at 25%. Levaquin has not been associated with vancomycin resistant enterococci and has a low potential for antibiotic associated diarrhea.

Levaquin is available on hospital formularies in Alaska and this can enhance continuity of care once patients are discharged.

Fred Meister of Schering Plough: Testified about Avelox. More than 66 million patients worldwide have used Avelox. The only difference in indications is that the FDA is the only monotherapy in quinolones for complicated intra-abdominal infections. There are several things important to note which are clinical efficacy, safety, and preponderance for developing resistant organisms. The Infectious Disease Society of American in conjunction with the American Thoracic Society has issued evidence-based consensus guidelines published in March 2007. These guidelines are the accepted standard of use and are significant in their impact on patient care. They state that although the doses may lead to adequate outcomes, switching to a more potent agent may lead to stabilization or overall decrease in resistance rates. More active agents are listed as Avelox and Factive. These drugs are given preference for their decreased potential for resistance. Data suggests that resistance to macrolides and older fluoroquinolones, such as Cipro and Levofloxacin, result in clinical failure. Newer agents have not had reports of clinical failure in community acquired pneumonia patients even with bacteremia. This is with 500 and 750 mg doses. The Capri study compared Avelox and Levaquin with emphasis on safety. Incorporated in the study was efficacy. The outcome was that the only clinically significant difference was in Avelox at 400 mg q.d. showed more rapid clinical recovery rate than levofloxacin. The end point dictated by the FDA was test of cure at 5 to 21 days; there was no difference in this area. With 500 mg q.d. of Levaquin versus 400 mg of Avelox, there was not significant difference between overall drug related adverse events. The incidence of cardiac event was 1% in the Avelox group and 3.5% in the levofloxacin group. *C. difficile* was 0.5% with Avelox and 3% with levofloxacin. There is a preference for newer fluoroquinolones.

Dr. Sater presented information on the second generation quinolones. There are three available agents in this class. All are effective for UTI. Other indications vary by agent. Ciprofloxacin is the only one available in suspension. The adverse drug reaction profiles, drug interactions, warnings and contraindications are similar for drugs in this class. In April, there were 151 claims for this class. Ciprofloxacin generic tablets has 94% market share. This is one of the preferred agents, with the other being generic ofloxacin. The other 6% were for various Cipro products. Class effect was declared but ciprofloxacin product was preferentially preferred.

Dr. Brodsky asked what the three products in this class were, and Dr. Sater answered that they are ciprofloxacin, ofloxacin and Noroxin.

DR. BERGESON MOVED TO DECLARE A CLASS EFFECT. DR. KELLER SECONDED. MOTION PASSED UNANIMOUSLY.

Dr. Sater presented information about the third generation quinolones. There are three available agents in this class, of which two are widely used. The FDA approved indications are widely varied. There is no clinical evidence to suggest superiority of one agent over another for respiratory infections. Both agents are dosed once daily. The preferred agent is Levaquin. There were 183 claims last month for this class; 172 of those were for Levaquin and the other 11 were for Avelox. There was a brief discussion last year of the American Thoracic Society guidelines for community acquired pneumonia, and the motion was made to prefer Levaquin and this passed unanimously. Letters from William White, MD; Deanna McConnell, ANP; Kevin Tomera, MD; William Clark, MD; and Terry Lester, MD from the Alaska Hospitalist group all recommended Levaquin.

Dr. Demain spoke in favor of continuing last year's motion. Levaquin is on hospital formularies and these drugs are effective, in his view.

DR. DEMAIN MOVED TO DECLARE A CLASS EFFECT WITH LEVAQUIN AS A PREFERRED AGENT. DR. MACIEJEWSKI SECONDED. MOTION CARRIED UNANIMOUSLY.

Dr. Conright asked Dr. Sater about discussion of categories and first and second generation medications and the way the information is provided to the committee beforehand. She asked that the handouts match the typical flow of discussion at the meetings. Dr. Sater stated she would pass on that information. Dr. Polston asked for utilization statistics, which Dr. Sater offered to send in advance of the committee meetings also.

13. Re-review Hepatitis C Drugs

Mark Resnick, Medical Liaison/Pharmacist, Roche: Testified about Pegasys. Since its approval in 2002, Pegasys, in combination with Ribavirin has become the most prescribed treatment for patients with hepatitis C. The success of Pegasys can be attributed to the following: 1. Several of its FDA indications are unique to Pegasys; 2. Convincing clinical trial data has demonstrated the high published rates of sustained viral responses in hepatitis C; 3. Ease of use; 4. The unique pharmacokinetics; 5. The NIH has made Pegasys its agent of choice in the design of hepatitis C trials aimed at enhancing outcomes in difficult to treat patients. Pegasys gained the indication of treatment for adults with chronic hepatitis C infection who have compensated liver disease and have not been previously treated with interferon-alpha. Pegasys is the only pegylated interferon indicated by the FDA for patients with compensated liver disease and histological cirrhosis and patients co-infected with HIV and hepatitis C. Only Pegasys in combination with Ribavirin is FDA approved for Ribavirin dosages and genotype specific treatment durations recommended by the NIH. In their consensus guidelines, NIH recommended that patients with genotype 1 be treated for 48 weeks with doses of Ribavirin at 1000 to 1200 mg in combination with pegylated interferon. Patients with genotypes 2 and 3 may be treated for only 24 weeks with pegylated interferon and Ribavirin 800 mg. Abbreviated in patients with 2 and 3 genotype may enhance tolerability and reduce cost. These recommended are based on data specific to Pegasys. Chronic hepatitis B patients can also be treated with Pegasys. Seven studies describing Pegasys in the management of hepatitis have been published in the New England Journal of Medicine and other top tier medical periodicals. SVRs of up to 63% have been achieved with Pegasys and Ribavirin, which is the highest reported SVR in patients with chronic hepatitis C. Pegasys has been proven effective in difficult-to-treat patients with SVRs of up to 59% in patients with high viral loads and up to 52% in patients with cirrhosis and up to 40% in those co-infected with hepatitis C and HIV. Pegasys has recently recorded the highest SVRs to date in genotype 1 African-American patients in a study sponsored by the NIH. Pegasys plus Ribavirin was shown to be better tolerated than standard interferon plus Ribavirin and the incidence of some adverse events were significantly less with Pegasys-based therapy, specifically depression, myalgia, rigors and other symptoms. Ongoing long-term followup data reveal that 99% of patients achieving SVR with Pegasys remain virus-free up to five years after the end of their treatment period. This is packaged as a ready to use solution requiring no mixing or reconstitution in a pre-filled syringe which makes it easy for patients and providers to use. Standard weekly dose of 180 mcg provides consistent therapeutic levels throughout the dosing period. The fixed dose strategy is convenient to the physician and the patient.

Dr. Demain asked if Pegasys is indicated for Hepatitis D. Mr. Resnick stated that there is a unique indication for hepatitis B, but it is not indicated for patients infected with both hepatitis B and C. The indication is for antigen negative and antigen positive patients.

Isaac Lloyd, Schering Plough: Testified on behalf of PEG-Intron, pegylated interferon alpha-2-b. The advantages to this agent include overall response rate, low relapse rate and individualized weight-based dosing. The overall response rate, SVR, is 54% based on registration trials and 52% based in the package insert. The

Peg-Intron registration trial demonstrated a low relapse rate of 18%. The relapse rate is the number of patients who achieve viral negativity at the end of treatment, but they become viral positive after 24 weeks of followup. At a recent liver meeting, Dr. Jacobson presented a large hepatitis C trial ever done with approximately 5000 patients. This study was a weight-based dosing Ribavirin versus fixed dose weight Ribavirin with Peg-Intron. The relapse rates in that study was 15% for weight-based dose and 19% for fixed-dose Ribavirin. The FDA debriefing document for peg-interferon alpha-2-a demonstrated a relapse rate of 30%. This agent is dosed by weight at 1.5 mcg per kg. In published studies, Peg-Intron and Ribavirin demonstrated similar response rates regardless of weight. Two studies, both community based, looked at weight-based dosed Ribavirin with pegylated interferon showed no difference in sustained virological response across all weight categories. Peg-interferon alpha-2-a is given at a fixed dose of 180 mcg per weight for all patients. The FDA debriefing document in table 17 states that the heavier the patient, the lower the response rate is with peg-interferon alpha-2-a. This is not approved for co-infection, but there is published data showing Peg-Intron is effective for these patients.

Dr. Sater gave the First Health presentation on this class of medications. There are currently two agents available in this class with similar adverse drug reaction profiles, drug interactions, warnings and contraindications. Sustained virological response rates appear to be similar with both agents. In Alaska in April there were eight claims, with Pegasys with the preferred agent having seven claims. There was one claim for Peg-Intron. There was no discussion last year. Class effect was declared and the motion passed unanimously. Dr. Sahagun would like to see PEG-Intron added to the PDL. Drs. Livingston and McMahon would like both preferred as they see a distinct role for each drug.

DR. BERGESON MOVED TO DECLARE CLASS EFFECT. DR. BRIGGS SECONDED.

Dr. Demain stated that there are drugs not used by the committee that are used by certain specialities. The committees get their opinions and Dr. Demain asked how much weight to give those. Dr. Brodsky stated that if there were a lot of claims for this, that consideration would be valid. The burden for writing "medically necessary" would take care of this class well, but Dr. Brodsky stated that other classes with more claims would need to give weight to those comments. Dr. Conright asked if the value of the decision by the committee was high enough for eight claims. Dr. Sater stated that it is because it means thousands of dollars a month. Treating a patient for one year with hepatitis costs approximately $15,000. Dr. Brodsky stated that there are more patients with potential for treatment, also.

MOTION CARRIED WITH TWO OPPOSED.

13. Re-Review of Ribavirin

There was no public comment for this class.

Dr. Sater gave the First Health Presentation for this class. There are two branded and one generic ribavirin products. The efficacy, adverse drug reaction profiles, drug interactions, warnings and contraindications are similar for both agents. There were nine claims for ribavirin in Alaska with five for the preferred generic ribavirin and four for Ribasphere. There was no discussion last year. A class effect was declared, and the motion passed unanimously.

DR. KILEY MOVED TO CONSIDER THIS A CLASS EFFECT. DR. BERGESON SECONDED.

Dr. Brodsky asked if ribavirin could be used with either interferon. Dr. Sater stated that they could and that Dr. Sahagun concurred with this, as long as there is a ribavirin product available.

MOTION PASSED UNANIMOUSLY.

Dr. Demain asked the committee to go back to the discussion of long-acting bronchodilators. He pointed out that there is a new inhalation product available, Brovana. This has limited use, but it was not discussed. He asked if the motion to declare class effect would include the nebulized form. This will be almost exclusively for COPD patients.

Dr. Sater stated that the motion will include Brovana, but it may not be included as part of the bid package. It may be a preferred agent, or not. There have been no claims for this medication yet. Dr. Demain pointed out that providers can write "medically necessary" since there will probably not be many claims.

14. Final Comments by Chair or other members

The committee realized that the minutes sent to the committee for review are from January 2006, and the committee needs those from January 2007. Those will be reviewed at the next meeting in September. He states that there were no noted errors in the April 2007 minutes. Those were adopted unanimously.

Dr. Brodsky pointed out that this is the last session of the spring, with no further meeting until Fall 2007.

Mr. Campana reported that there will be some classes combined and only four meetings next year. These will be September, November, January, and April, but more information will follow on those. There are new classes, which Mr. Campana read: Low molecular weight heparins, the hemopoietic agents, growth hormone, benzyl peroxide-clindamycin combination, low sedating antihistamines and otic quinolones.

Dr. Curtiss asked about anti-psychotics, which Mr. Campana reported are not yet on the agenda for review. Dr. Brodsky stated that four meetings are based on time-efficient meetings.

Mr. Campana states that the State has figured out a way to pay the honorarium for committee members. Members wishing to receive honorarium were asked to turn in a W-9 form. He thanked all for their participation in the P&T Committee, now in its fourth year. Dr. Brodsky offered his thanks also to the committee members and wished them all a good summer.

Dr. Sater stated that she will not announce the choices made during the course of the meeting at the end of the meeting to allow for more reflection and best use of time. Those will be emailed the week following each meeting.

MEETING ADJOURNED AT 11:30 AM.